

tivities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

“(3) MEMBERSHIP.—

“(A) FEDERAL MEMBERS.—The Task Force shall be composed of each of the following Federal members, or the designees of such members:

“(i) The Director of the Centers for Disease Control and Prevention.

“(ii) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the directors of such other appropriate national research institutes.

“(iii) The Commissioner of Food and Drugs.

“(iv) The Director of the Office on Women’s Health.

“(v) The Director of the National Vaccine Program Office.

“(vi) The head of any other research-related agency or department not described in clauses (i) through (v) that the Secretary determines appropriate, which may include the Department of Veterans Affairs and the Department of Defense.

“(B) NON-FEDERAL MEMBERS.—The Task Force shall be composed of each of the following non-Federal members, including—

“(i) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

“(ii) nonprofit organizations with expertise related to the health of women and children;

“(iii) relevant industry representatives; and

“(iv) other representatives, as appropriate.

“(C) LIMITATIONS.—The non-Federal members described in subparagraph (B) shall—

“(i) compose not more than one-half, and not less than one-third, of the total membership of the Task Force; and

“(ii) be appointed by the Secretary.

“(4) TERMINATION.—

“(A) IN GENERAL.—Subject to subparagraph (B), the Task Force shall terminate on the date that is 2 years after the date on which the Task Force is established under paragraph (1).

“(B) EXTENSION.—The Secretary may extend the operation of the Task Force for one additional 2-year period following the 2-year period described in subparagraph (A), if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

“(5) MEETINGS.—The Task Force shall meet not less than 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under paragraph (2).

“(6) TASK FORCE REPORT TO CONGRESS.—Not later than 18 months after the date on which the Task Force is established under paragraph (1), the Task Force shall prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that includes each of the following:

“(A) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies.

“(B) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research.

“(C) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women.

“(D) Identification of Federal activities, including—

“(i) the state of research on pregnancy and lactation;

“(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

“(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

“(iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities.

“(E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

“(b) CONFIDENTIALITY.—Nothing in this section shall authorize the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

“(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN AND LACTATING WOMEN IN RESEARCH.—

“(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act [Dec. 13, 2016], the Secretary, considering any recommendations of the Task Force available at such time and in consultation with the heads of relevant agencies of the Department of Health and Human Services, shall, as appropriate, update regulations and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research.

“(2) CRITERIA FOR EXCLUDING PREGNANT OR LACTATING WOMEN.—In updating any regulations or guidance described in paragraph (1), the Secretary shall consider any appropriate criteria to be used by institutional review boards and individuals reviewing grant proposals for excluding pregnant women or lactating women as a study population requiring additional protections from participating in human subject research.”

INAPPLICABILITY TO CURRENT PROJECTS

Pub. L. 103-43, title I, §133, June 10, 1993, 107 Stat. 135, provided that: “Section 492B of the Public Health Service Act, as added by section 131 of this Act [42 U.S.C. 289a-2], shall not apply with respect to projects of clinical research for which initial funding was provided prior to the date of the enactment of this Act [June 10, 1993]. With respect to the inclusion of women and minorities as subjects in clinical research conducted or supported by the National Institutes of Health, any policies of the Secretary of Health and Human Services regarding such inclusion that are in effect on the day before the date of the enactment of this Act shall continue to apply to the projects referred to in the preceding sentence.”

§ 289b. Office of Research Integrity

(a) In general

(1) Establishment of Office

Not later than 90 days after June 10, 1993, the Secretary shall establish an office to be known as the Office of Research Integrity (referred to in this section as the “Office”), which shall be established as an independent entity in the Department of Health and Human Services.

(2) Appointment of Director

The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct. The Secretary shall carry out this section acting through the Director of the Of-

fice. The Director shall report to the Secretary.

(3) Definitions

(A) The Secretary shall by regulation establish a definition for the term “research misconduct” for purposes of this section.

(B) For purposes of this section, the term “financial assistance” means a grant, contract, or cooperative agreement.

(b) Existence of administrative processes as condition of funding for research

The Secretary shall by regulation require that each entity that applies for financial assistance under this chapter for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity;

(2) an agreement that the entity will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this chapter that appears substantial; and

(3) an agreement that the entity will comply with regulations issued under this section.

(c) Process for response of Director

The Secretary shall by regulation establish a process to be followed by the Director for the prompt and appropriate—

(1) response to information provided to the Director respecting research misconduct in connection with projects for which funds have been made available under this chapter;

(2) receipt of reports by the Director of such information from recipients of funds under this chapter;

(3) conduct of investigations, when appropriate; and

(4) taking of other actions, including appropriate remedies, with respect to such misconduct.

(d) Monitoring by Director

The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

(e) Protection of whistleblowers

(1) In general

In the case of any entity required to establish administrative processes under subsection (b), the Secretary shall by regulation establish standards for preventing, and for responding to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith—

(A) made an allegation that the entity, its officials or agents, has engaged in or failed

to adequately respond to an allegation of research misconduct; or

(B) cooperated with an investigation of such an allegation.

(2) Monitoring by Secretary

The Secretary shall by regulation establish procedures for the Director to monitor the implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

(3) Noncompliance

The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in retaliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being provided by the Secretary for such project, or other actions as appropriate.

(July 1, 1944, ch. 373, title IV, § 493, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 874; amended Pub. L. 103-43, title I, §§ 161, 163, June 10, 1993, 107 Stat. 140, 142.)

CODIFICATION

June 10, 1993, referred to in subsec. (a)(1), was in the original “the date of enactment of this section” which was translated as meaning the date of enactment of Pub. L. 103-43, which amended this section generally, to reflect the probable intent of Congress.

AMENDMENTS

1993—Pub. L. 103-43, § 161, amended section generally. Prior to amendment, section read as follows:

“(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity—

“(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of scientific fraud in connection with biomedical and behavioral research conducted at or sponsored by such entity; and

“(2) will report to the Secretary any investigation of alleged scientific fraud which appears substantial.

“(b) The Director of NIH shall establish a process for the prompt and appropriate response to information provided the Director of NIH respecting scientific fraud in connection with projects for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such fraud.”

Subsec. (e). Pub. L. 103-43, § 163, added subsec. (e).

REGULATIONS

Pub. L. 103-43, title I, § 165, June 10, 1993, 107 Stat. 143, provided that:

“(a) ISSUANCE OF FINAL RULES.—

“(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act [June 10, 1993], the Secretary shall, subject to paragraph (2), issue the final rule for each regulation required in section 493 or 493A of the Public Health Service Act [42 U.S.C. 289b, 289b-1].

“(2) DEFINITION OF RESEARCH MISCONDUCT.—Not later than 90 days after the date on which the report required in section 162(e) [107 Stat. 142] is submitted to the Secretary, the Secretary shall issue the final rule for the regulations required in section 493 of the Public Health Service Act with respect to the definition of the term ‘research misconduct’.

“(b) APPLICABILITY TO ONGOING INVESTIGATIONS.—The final rule issued pursuant to subsection (a) for investigations under section 493 of the Public Health Service Act [42 U.S.C. 289b] does not apply to investigations commenced before the date of the enactment of this Act [June 10, 1993] under authority of such section as in effect before such date.

“(c) DEFINITIONS.—For purposes of this section:

“(1) The term ‘section 493 of the Public Health Service Act’ means such section [42 U.S.C. 289b] as amended by sections 161 and 163 of this Act, except as indicated otherwise in subsection (b).

“(2) The term ‘section 493A of the Public Health Service Act’ means such section [42 U.S.C. 289b–1] as added by section 164 of this Act.

“(3) The term ‘Secretary’ means the Secretary of Health and Human Services.”

§ 289b–1. Protection against financial conflicts of interest in certain projects of research

(a) Issuance of regulations

The Secretary shall by regulation define the specific circumstances that constitute the existence of a financial interest in a project on the part of an entity or individual that will, or may be reasonably expected to, create a bias in favor of obtaining results in such project that are consistent with such financial interest. Such definition shall apply uniformly to each entity or individual conducting a research project under this chapter. In the case of any entity or individual receiving assistance from the Secretary for a project of research described in subsection (b), the Secretary shall by regulation establish standards for responding to, including managing, reducing, or eliminating, the existence of such a financial interest. The entity may adopt individualized procedures for implementing the standards.

(b) Relevant projects

A project of research referred to in subsection (a) is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

(c) Identifying and reporting to Secretary

The Secretary shall by regulation require that each entity described in subsection (a) that applies for assistance under this chapter for any project described in subsection (b) submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect an administrative process under subsection (a) to identify financial interests (as defined under subsection (a)) that exist regarding the project; and

(2) an agreement that the entity will report to the Secretary such interests identified by the entity and how any such interests identified by the entity will be managed or eliminated in order that the project in question will be protected from bias that may stem from such interests; and

(3) an agreement that the entity will comply with regulations issued under this section.

(d) Monitoring of process

The Secretary shall monitor the establishment and conduct of the administrative process established by an entity pursuant to subsection (a).

(e) Response

In any case in which the Secretary determines that an entity has failed to comply with subsection (c) regarding a project of research described in subsection (b), the Secretary—

(1) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest (as defined under subsection (a)) in each public presentation of the results of such project; and

(2) may take such other actions as the Secretary determines to be appropriate.

(f) Definitions

For purposes of this section:

(1) The term “financial interest” includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

(2) The term “assistance”, with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

(July 1, 1944, ch. 373, title IV, §493A, as added Pub. L. 103–43, title I, §164, June 10, 1993, 107 Stat. 142.)

REGULATIONS

Final rule for regulations required in this section to be issued not later than 180 days after June 10, 1993, see section 165 of Pub. L. 103–43, set out as a note under section 289b of this title.

§ 289c. Research on public health emergencies

If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control and Prevention, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) shall expedite the review by advisory councils under section 284a of this title and by peer review groups under section 289a of this title of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 6101 of title 41 respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.